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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/582,534 06/27/00 POIRIER

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EXAMINER

HM22/0829

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HOLLAND & KNIGHT LLP  
ONE ATLANTIC CENTER  
SUITE 2000  
ATLANTA GA 30309-3400

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

08/29/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/582,534

Applicant(s)

POIRIER ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 82-133 is/are pending in the application.
- 4a) Of the above claim(s) 133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-88, 91-94, 97-106 and 109-132 is/are rejected.
- 7) ☒ Claim(s) 89, 90, 95, 96, 107 and 108 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER  
PATENT ANALYST

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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#### DETAILED ACTION

1. Applicant's election of Group III, claims 82-132 in Paper No. 5 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 133 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

The election of species in Paper 8 with traverse is further noted. Claim 133 was inadvertently included with the election of species, but since claim 133 was not a member claim of Group III in the restriction requirement mailed 12/6/00, the election of species for claim 133 will not be considered.

Applicant argues the election of species as follows: since claims 82-90 are directed to a recombinant host cell, claims 91-96 are drawn to a genetically transformed plant cell, claims 97-108 are drawn to a genetically transformed plant, claims 109-115 are drawn to a method of preparing host cells, claims 116-120 are drawn to a method for preparing a polyhydroxyalkanoate by a cell, claims 121-127 are drawn to methods for preparing a polyhydroxyalkanoate by a cell, and claims 128-132 are drawn to methods for preparing polyhydroxyalkanoate by a cell, the lines drawn by examiner for the election of species are not correct. Applicant argues that the limitations in claim 82 are shared with all of claims 82-96, the limitations in claim 97 are shared

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with all of claims in 97-108, the limitations in claim 121 are shared with all of claims 121-127 and the limitations in 128 are shared by all of claims 128-132. Applicant argues that "In determining whether to require an election of species on the basis that the species in a claim are either independent or distinct, the Examiner has to ascertain that the claims to be restricted are drawn to different species which are mutually exclusive (MPEP 806.04(f)). The Examiner needs to ascertain that one claim recites limitations which are found in a first species but not in a second species and vice versa (MPEP 806.04 (f)). "

In response, the election of species is still proper for the following reasons: Examiner agrees that the way the election was written in Paper 6 did not clearly address the distinction of claims into the sub-groups 82-96, 97-108, 121-127 and 128-132 noted by Applicant as sharing common limitations of the parent claim of each group, and that the way the election was written therefore did not directly address these subgroups as being generic. It was felt that such distinction was unnecessary since within each such generic sub-group of Group III, there are individual species which have mutually exclusive characteristics. For example, the *Saccharomyces cerevisiae* of claim 84 does have mutually exclusive characteristics from the other species of fungal cells claimed in claim 84. Although all of the claimed species in claim 84 share common limitations with the parent claim 82 (ie. the occurrence of a non-naturally occurring fusion protein, etc.) and as such share these broader limitations with the other claims in the sub-group of claims 82-96, this does not refute the point that all the claimed species in claim 84 are independent species. This reasoning may be further applied to the other claims in which the

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election of species was required independently: claims 113, 124, 86, 115, 126, 92, 119, 98, 100, 102, 104, 127, 131 and 132. Examiner believes that the burden of MPEP 806.04(f) is thus met. Further, the election of species was made with the consideration of MPEP 806.04(h) as well. Specifically, each of the listed species in the Markush claims under election are patentably distinct species in view of the other listed species within each Markush group. As such, the election was primarily made to reduce the burden of searching the large number of claimed, patentably distinct species. However, upon reconsideration of the burden of search, the election of species for the promoters will not be required nor for the specific hydroxydodecanoic acids.

Therefore, claim 84 will be considered for *Saccharomyces cerevisiae*, claim 113 for *Saccharomyces cerevisiae*, claim 124 for *Saccharomyces cerevisiae*, claim 86 for canola/oilseed rape, claim 92 for canola/oilseed rape, claim 98 for canola/oilseed rape, claim 115 for canola/oilseed rape, claim 119 for canola/oilseed rape, and claim 130 for canola/oilseed rape. (NOTE: claim 130 was inadvertently omitted from the election of species requirement mailed 3/14/01. However, in view of Applicant's other elections of canola/oilseed rape for claims 86, 92, 98, 115 and 119, it is assumed that Applicant would have also elected canola/oilseed rape for claim 130. If this assumption is in error, please respond with an alternate election in the response to this Official Action.)

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***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 82-86, 91-92, 97-104 and 109-132 rejected under 35 U.S.C. 103(a) as being unpatentable over Bright et al. (WO92/19747, IDS Reference B5) and Hayashi et al. (IDS Reference C4) in view of Hahn et al. (International Symposium on Bacterial Polyhydroxyalkanoates '96, (abstract and poster), 16 pgs., 1996, "Peroxisomal Localization of PHA Synthesis in Eukaryotic Cells"), the above combination further in view of Somerville et al. (U.S. Patent 5,801,026), Hitz (U.S. Patent RE37,317), Elgersma et al. (JBC 271, 42, p. 26375-26382, 1997), Verleur et al. (Eur. J. Biochem. 247, 972-980 (1997)), Gengenbach et al. (U.S.

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Patent 6,146,867), Tomes et al. (U.S. Patent 6,258,999 B1), and Bright et al. (U.S. Patent 6,175,061 B1).

Bright et al. is relied upon to teach production of polyhydroxyalkanoates in plants, such as the "oil-seed" crops including oilseed rape, canola, soya and sunflower (page 3, lines 24-31). They do not necessarily teach a fusion comprising a peroxisome targeting protein for synthesis of such polyhydroxyalkanoates.

Hayashi et al. is relied upon to teach fusion proteins for transport to peroxisomes in plants. They do not necessarily teach fusion of polyhydroxyalkanoates.

Elgersma et al. and Verleur et al. are relied upon to teach peroxisomal targeting and signals to peroxisomes in *Saccharomyces*. They do not necessarily teach fusion of polyhydroxyalkanoates for production in the peroxisome. Verleur et al. also teaches growth of *Saccharomyces* in specific nutrient, oleate, growth conditions.

Hahn et al. is relied upon to teach peroxisomal localization of PHA synthesis. (Note, a copy of this reference will be furnished via fax to Applicant).

Hitz et al. is relied upon to teach expression of an acyl-ACP thioesterase in regulation of fatty acid content in the oils of soybean and canola plants.

Somerville et al. is relied upon to teach expression of a fatty acyl hydroxylase in regulation of hydroxylase fatty acids and derivatives in plants.

Gengenbach et al. (U.S. Patent 6,146,867) is relied upon to teach use of constitutive plant promoters.

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Tomes et al. (U.S. Patent 6,258,999 B1) is relied upon to teach inducible plant promoters.

Bright et al. (U.S. Patent 6,175,061 B1) is relied upon to teach tissue specific plant promoters.

It would have been prima facie obvious at the time the invention was made for one of ordinary skill in the art to make a recombinant host cell, a plant such as canola/oilseed rape or fungus such as *Saccharomyces cerevisiae*, having a fusion protein comprising a peroxisome targeting protein subunit and a nucleic acid encoding a polyhydroxyalkanoate synthase protein subunit. It would have been further obvious to make such a recombinant host cell having either an acyl-ACP thioesterase or fatty acyl hydroxylase and wherein the nucleic acids are expressed from constitutive, inducible or tissue specific promoters.

One of ordinary skill in the art would have been motivated to make a recombinant plant, such as canola/oilseed rape, or *Saccharomyces cerevisiae* having a fusion protein comprising a peroxisome targeting protein subunit and a nucleic acid encoding a polyhydroxyalkanoate synthase protein subunit since (1) peroxisome targeting subunits were well-known in the art as exemplified by Hayahi et al. in plants and Elgersma et al. and Verleur et al. in *Saccharomyces cerevisiae*; (2) polyhydroxyalkanoate production in plants was well known in the art (taught by Bright et al.); and (3) Hahn et al. taught motivation for synthesis of PHA via peroxisomal localization.

One of ordinary skill in the art would have had an expectation of success to localize nucleic acid sequences to the peroxisome via making a fusion of a peroxisomal signal and a



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nucleic acid expressing a polyhydroxyalkanoate since (1) peroxisomal targeting signals were well-known in the art at the time the invention was made, (2) synthesis of polyhydroxyalkanoates was well-known in the art at the time the invention was made, and (3) Hahn taught localization of polyhydroxyalkanoate synthesis via peroxisome targeting. One of ordinary skill in the art would have further had an expectation of success to express an acyl-ACP thioesterase or fatty acyl hydroxylase recombinantly and via use of expression vectors having well-known plant promoters as taught by Gengenbach et al., Tomes et al., and Bright et al.

5. Claims 89, 90, 95, 96, 107 and 108 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt  
August 27, 2001



**ANDREW WANG**  
**PRIMARY EXAMINER**